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# California Regional Water Quality Control Board

## Central Valley Region



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**DATE:** 2 July 1998

**SIGNATURE:** 

**SUBJECT:** PRECEDENT FOR USE OF THE ONE-IN-A-MILLION CANCER RISK LEVEL

### Request:

What risk level for human cancer should be used in selecting human health-based criteria to interpret the narrative water quality objectives for toxicity in our Basin Plans?

### Response:

The one-in-a-million ( $10^{-6}$ ) cancer risk level has historically formed the basis of human health protective numerical water quality limits in California. Therefore this risk level should be the reference risk level that governs the selection of human health-based criteria to implement the narrative toxicity objective.

### Discussion:

Chapter III of the Water Quality Control Plan (Basin Plan) for the Sacramento and San Joaquin River Basins contains the following water quality objectives for toxicity in inland surface water and in groundwater, respectively:

“All waters shall be maintained free of toxic substances in concentrations that produce detrimental physiological responses in human, plant, animal, or aquatic life. This objective applies regardless of whether the toxicity is caused by a single substance or the interactive effect of multiple substances. Compliance with this objective will be determined by analyses of indicator organisms, species diversity, population density, growth anomalies, and biotoxicity tests of appropriate duration or other methods as specified by the Regional Water Board. The Regional Water Board will also consider all material and relevant information submitted by the discharger and other interested parties and numerical criteria and guidelines for toxic substances developed by the State Water Board, the California Office of Environmental Health Hazard Assessment, the California Department of Health Services, the U.S. Food and Drug Administration, the National Academy of Sciences, the U.S. Environmental Protection Agency, and other appropriate organizations to evaluate compliance with this objective.”

“Ground waters shall be maintained free of toxic substances in concentrations that produce detrimental physiological responses in human, plant, animal, or aquatic life associated with designated beneficial use(s). This objective applies regardless of whether the toxicity is caused by a single substance or the interactive effect of multiple substances.”

Chapter IV of the Basin Plan contains the Board's *Policy for Application of Water Quality Objectives*, which contains the following language on interpretation of narrative objectives:

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“To evaluate compliance with the narrative water quality objectives, the Regional Water Board considers, on a case-by-case basis, direct evidence of beneficial use impacts, all material and relevant information submitted by the discharger and other interested parties, and relevant numerical criteria and guidelines developed and/or published by other agencies and organizations (e.g., State Water Board, California Department of Health Services, California Office Of Environmental Health Hazard Assessment, California Department of Toxic Substances Control, University of California Cooperative Extension, California Department of Fish and Game, USEPA, U.S. Food and Drug Administration, National Academy of Sciences, U.S. Fish and Wildlife Service, Food and Agricultural Organization of the United Nations). In considering such criteria, the Board evaluates whether the specific numerical criteria, which are available through these sources and through other information supplied to the Board, are relevant and appropriate to the situation at hand and, therefore, should be used in determining compliance with the narrative objective. For example, compliance with the narrative objective for taste and odor may be evaluated by comparing concentrations of pollutants in water with numerical taste and odor thresholds that have been published by other agencies. This technique provides relevant numerical limits for constituents and parameters which lack numerical water quality objectives. To assist dischargers and other interested parties, the Regional Water Board staff has compiled many of these numerical water quality criteria from other appropriate agencies and organizations in the Central Valley Regional Water Board's staff report, *A Compilation Of Water Quality Goals*. This staff report is updated regularly to reflect changes in these numerical criteria.”

Nearly identical language to the above appears in the Tulare Lake Basin Plan.

In waters for which the beneficial use of Municipal and Domestic Supply (MUN) has been designated, toxicity to humans is the main focus of these narrative toxicity objectives. The Basin Plans also contain a requirement that MUN designated waters not contain chemical constituents in excess of California maximum contaminant levels (MCLs) for drinking water. This is reasonable, because water taken from these sources is required to meet MCLs when delivered to customers of water supply systems. MCLs are adopted by the California Department of Health Services (DHS) and are designed to apply to water within a drinking water distribution system and at the tap. In these locations, MCLs are legally enforceable pursuant to the Health and Safety Code. Primary MCLs are derived from human health criteria. However, virtually all Primary MCLs are derived by balancing the health effects information with technologic and economic considerations that directly relate to providing that water via conventional domestic and municipal drinking water supply systems. These constraints on MCL derivation may result in limits that are not truly health protective. Therefore, care should be taken in applying Primary MCLs to implement the narrative toxicity objective for sources of drinking water (groundwater or surface water resources) pursuant to the Basin Plans and the Water Code. Compliance with MCLs and compliance with the narrative toxicity objective are separate requirements of the Basin Plans. Both must be met.

To ensure that compliance can be ascertained, MCLs are required to be set at or above commonly achievable analytical quantitation limits. In several cases, DHS has established MCLs at concentrations higher than health protective levels, where such levels are lower than analytical quantitation limits. The 1988 *Statement of Reasons* justifying the Primary MCL for the solvent carbon tetrachloride states:

“Based on the most appropriate animal study, the Department determined that the *de minimis* drinking water concentration for regulatory purposes is 0.0002 mg/l [0.2 ppb], more stringent than the current detection limit of 0.0005 mg/l [0.5 ppb]. Therefore, the Department proposes setting the MCL at the detection limit of 0.0005 mg/l [0.5 ppb].”

In 1989, DHS adopted the MCL for carbon tetrachloride at 0.5 ppb. Similarly, the 1988 *Statement of Reasons* justifying the Primary MCL for the solvent tetrachloroethylene (perchloroethylene or PCE) states:

“On the basis of the potency and exposure assessment, 2 ppb is recommended as the drinking water concentration associated with the *de minimis* excess cancer risk value of one case in one million persons. This value is typically assumed by federal and state regulatory agencies for involuntary exposures to environmental pollutants.”

However, in 1989, DHS adopted the Primary MCL for PCE at 5 ppb, equal to the analytical quantitation limit established at that time by USEPA. From the above quoted documents, it is clear that the intent of DHS was to adopt the *de minimis* cancer risk values as MCLs if analytical quantitation limits had been lower. Since the adoption of both of these MCLs, analytical quantitation limits have improved, such that their respective health-based levels can be reliably measured. The technologic constraint of analytical quantitation is no longer germane. Therefore, it is no longer reasonable to rely on outdated analytical quantitation limits as substitutes for truly health-based criteria when implementing the narrative water quality objective for toxicity.

Another example of incorrect MCL application is the use of the total trihalomethane (THM) MCL for the protection of groundwater quality from chloroform, bromoform, bromodichloromethane and dibromochloromethane. These four chemicals are called “trihalomethanes,” and are considered to be probable and possible human carcinogens. They are formed in drinking water by the action of chlorine, used for disinfection, on organic matter present in the raw source water. The total THM Primary MCL is 100 mg/l, seventeen to 370 times higher than one-in-a-million incremental cancer risk estimates published by Office of Environmental Health Hazard Assessment (OEHHA) and the U.S. Environmental Protection Agency (USEPA). USEPA has stated that the MCL for total THMs was based mainly on technologic and economic considerations. The MCL for total THMs was derived by balancing the benefit provided by the chlorination process--elimination of pathogens in drinking water--with the health threat posed by the trihalomethane byproducts of this process and the cost associated with conversion to non-chlorine disinfection methods. In the case of groundwater protection, this type of cost/benefit balancing is not germane. This water has not been and may not need to be chlorinated prior to domestic use.

The above discussion provides rationale for the use of purely health-based criteria, rather than MCLs, to implement the narrative toxicity objectives in the Basin Plans. In many cases there are several health-based criteria from which to choose. In May of 1994, representatives of the State and Regional Water Boards met with toxicologists and other representatives of the Department of Toxic Substances Control (DTSC) and OEHHA to discuss the use of toxicologic criteria in contaminated site assessment and cleanup. The group agreed on guidance parallel to that given on page 2-20 of DTSC's *Preliminary Endangerment Assessment Guidance Manual* (January 1994). When selecting numerical limits from the literature to implement health based narrative water quality objectives or when selecting criteria for use in health risk assessments, limits should be used in the following hierarchy:

1. Cancer potency slope factors and reference doses promulgated into California regulations.
2. Cancer potency slope factors and reference doses used to develop environmental criteria promulgated into California regulations. Examples include criteria used in deriving State drinking water standards and air “toxic hot spots” regulations. The entirely health-based dose criteria should be used, and not necessarily the resulting risk management environmental concentration criteria (e.g., the RfD rather than the MCL).
3. Cancer potency slope factors and reference doses from USEPA's Integrated Risk Information System (IRIS).

4. Cancer potency slope factors or reference doses from USEPA's *Health Effects Assessment Summary Tables (Health Advisories)*, the most current edition.

Cancer potency factors in the first two categories are summarized in California Environmental Protection Agency Criteria for Carcinogens, OEHHA (1994).

Regulations implementing Proposition 65 cite the one-in-a-hundred-thousand ( $10^{-5}$ ) risk level for carcinogens. However, the intent of this initiative statute is public notice prior to exposure to certain chemicals and the prohibition of specific discharges of these chemicals. It is not the intent of Proposition 65 to establish levels of involuntary environmental exposure that are considered "safe." Therefore, Proposition 65 does not provide a relevant precedent for determining compliance with the narrative toxicity objective in our Basin Plans.

The  $10^{-6}$  risk level has long formed the basis of water-related health-protective regulatory decision-making in California. The following are some of the more significant instances:

1. DHS *Statement of Reasons* documents that justify Primary MCLs for carcinogenic substances all use the  $10^{-6}$  risk level for lifetime exposure as the basis from which the MCLs were derived. In the two examples quoted above, DHS describes the  $10^{-6}$  risk level as the *de minimis* excess cancer risk value" which is "typically assumed by federal and state regulatory agencies for involuntary exposures to environmental pollutants." MCLs for carcinogens deviate from the  $10^{-6}$  risk level only where technologic or economic factors prevent the use of this level.
2. DHS "action levels" for drinking water are also set at the  $10^{-6}$  risk level unless technologic or economic factors prevent using this level, as with the Primary MCLs.
3. The DTSC *Preliminary Endangerment Assessment Guidance Manual* [page 2-26] states that "[i]n general, a risk estimation greater than [sic]  $10^{-6}$  or a hazard index greater than 1 indicate the presence of contamination which may pose a significant threat to human health."
4. USEPA National Ambient Water Quality Criteria, recommended to protect human health from carcinogenic chemicals in surface waters, historically have presented  $10^{-5}$ ,  $10^{-6}$ , and  $10^{-7}$  risk estimates (with a geometric mean of  $10^{-6}$ ) in water.
5. Clean Water Act water quality criteria promulgated on California waters by USEPA in the National Toxics Rule (NTR) [40 CFR 131.36(d)(10)(iii)] and proposed for promulgation in the California Toxics Rule (CTR) [62 FR 150, page 42208; 40 CFR 131.38(d)(4)] state that "[t]he human health criteria shall be applied at the State-adopted  $10^{-6}$  risk level." These NTR criteria are a component of California's water quality standards for surface waters. If adopted by USEPA, the proposed CTR criteria will become a component of California's water quality standards for surface waters.
6. *Functional Equivalent Documents* formally adopted by the State Water Board that provide background and justification for the California Ocean Plan and the former California Inland Surface Waters and Enclosed Bays and Estuaries Plans all cited the  $10^{-6}$  risk level as the basis of human health protective water quality objectives for carcinogens.
7. Public Health Goals for drinking water, adopted by OEHHA in December 1997, are based on the  $10^{-6}$  risk level for carcinogens, "a level that has been considered negligible or *de minimis*," and a 70 year exposure period.

8. In recent enforcement decisions regarding an off-site chlorinated solvent plume from Mather Air Force Base, the Central Valley Regional Water Quality Control Board stated that replacement water supply must be provided when the level of carcinogenic chemicals is detected and confirmed at or above concentrations that represent  $10^{-6}$  lifetime cancer risk levels in individual wells. This decision implements the narrative toxicity objective for groundwater from the Water Quality Control Plan (Basin Plan) for the Sacramento River and San Joaquin River Basins.
9. Cleanup and Abatement Order No. 92-707 adopted by the Central Valley Regional Water Quality Control Board established cleanup levels for groundwater at the Southern Pacific Transportation Company, Tracy Yard, San Joaquin County at the  $10^{-6}$  lifetime cancer risk levels for carcinogens, based on the narrative toxicity objective for groundwater from the Basin Plan for the Sacramento River and San Joaquin River Basins.

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